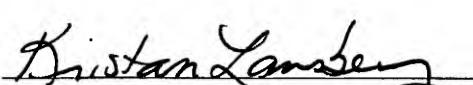


|   |   |  |
|---|---|--|
| <b>TRANSMITTAL LETTER TO THE UNITED STATES<br/>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br/>CONCERNING A FILING UNDER 35 U.S.C. 371</b>   |   | ATTORNEY'S DOCKET NUMBER   |
|   |   | 18724.009  |
| INTERNATIONAL APPLICATION NO.<br>PCT/EP2004/000109  | INTERNATIONAL FILING DATE<br>9 January 2004 | U.S. APPLICATION NO. (If known, see 37 CFR 1.51)<br><b>To Be Assigned</b> <b>104563956</b> |
|   |   | PRIORITY DATE CLAIMED<br>11 July 2003  |
| <b>TITLE OF INVENTION</b><br><b>Autologous Self-Tolerance Inducing Cells of Monocytic Origin and Their Use in Pharmaceutical Preparations</b>   |   |  |
| <b>APPLICANT(S) FOR DO/EO/US</b><br><b>Bernd Karl Friedrich KREMER, Fred FÄNDRICH, and Maren SCHULZE</b>  |   |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |   |  |
| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US); however, a courtesy copy is attached.</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4) and a courtesy copy is enclosed.</li> </ol> </li> <li>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol> |   |  |
| <b>Items 11 to 20 below concern document(s) or information included:</b>  |   |  |
| <ol style="list-style-type: none"> <li>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input checked="" type="checkbox"/> A preliminary amendment.</li> <li>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</li> <li>15. <input type="checkbox"/> A substitute specification.</li> <li>16. <input checked="" type="checkbox"/> A power of attorney and/or change of address letter.</li> <li>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.</li> <li>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</li> <li>20. <input checked="" type="checkbox"/> Other items or information: a Second and Supplementary Notice Informing the Applicant of the Communication of the International Application (to Designated Offices which Apply the 30 Month Time Limited Under Article 22(1)), a Notification of the Recording of a Change, an Information Concerning Elected Offices Notified of Their Election, and a First Notice Informing the Applicant of the Communication of the International Application (to Designated Offices which do not Apply the 30 Month Time Limit Under Article 22(1)), a letter to WIPO requesting change of inventor Maren RUHNKE's name to Maren SCHULZE, and a copy of Form PCT/IPEA/409 (International Preliminary Report on Patentability)</li> </ol>   |   |  |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450 Alexandria, VA 2313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

|   |              |   |            |                                       |                        |
|---|--------------|---|------------|---------------------------------------|------------------------|
| U.S. APPLICATION NO. (if known, see 37 CFR 1.5)<br>To Be Assigned <b>10/563956</b>  |              | INTERNATIONAL APPLICATION NO.<br>PCT/EP2004/000109                            |            | ATTORNEY'S DOCKET NUMBER<br>18724.009 |                        |
| 21. The following fees are submitted:   |              |   |            | <b>Applicant use</b>                  | <b>Office use only</b> |
| <input checked="" type="checkbox"/> a) Basic national fee.....\$300.00  |              |   |            | \$ 300.00                             |                        |
| <input checked="" type="checkbox"/> b) Examination fee.....\$200.00   |              |   |            | \$ 200.00                             |                        |
| <input checked="" type="checkbox"/> c) Search fee .....\$500.00   |              |   |            | \$ 500.00                             |                        |
| <b>TOTAL OF ABOVE CALCULATIONS = \$1000.00</b>  |              |   |            | <b>\$ 1,000.00</b>                    |                        |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (including sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.  |              |   |            |                                       |                        |
| Total Sheets  | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) |            | RATE                                  |                        |
| ** - 100 =  | 0 / 50 =     | 0   |            | x \$250.00                            | \$ 0.00                |
| Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).   |              |   |            | \$ 0.00                               |                        |
| CLAIMS  | NUMBER FILED | NUMBER EXTRA  | RATE       |                                       |                        |
| Total claims  | 40 - 20 =    | 20  | x \$50.00  | \$ 1,000.00                           |                        |
| Independent claims  | 8 - 3 =      | 5   | x \$200.00 | \$ 1,000.00                           |                        |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)   |              |   |            | + \$360.00                            | \$                     |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>  |              |   |            | <b>\$ 2,000.00</b>                    |                        |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by ½.  |              |   |            | \$                                    |                        |
|   |              |   |            | <b>SUBTOTAL =</b>                     | <b>\$ 3,000.00</b>     |
| Processing fee of <b>\$130.00</b> for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).  |              |   |            | +                                     | \$                     |
|   |              |   |            | <b>TOTAL NATIONAL FEE =</b>           | <b>\$ 3,000.00</b>     |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.21). <b>\$40.00</b> per property   |              |   |            | +                                     | \$                     |
|   |              |   |            | <b>TOTAL FEES ENCLOSED =</b>          | <b>\$ 3,000.00</b>     |
|   |              |   |            | Amount to be refunded:                | \$                     |
|   |              |   |            | Amount to be charged                  | \$                     |
| <p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. 50-2387 in the amount of <u>\$ 3,000.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-2387. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.</p> |              |   |            |                                       |                        |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.  |              |   |            |                                       |                        |
| SEND ALL CORRESPONDENCE TO:   |              |   |            |                                       |                        |
| ARNOLD & PORTER LLP   |              |   |            |                                       |                        |
| Attn: IP Docketing  |              |   |            |                                       |                        |
| 555 Twelfth Street, N.W.  |              |   |            |                                       |                        |
| Washington, DC 20004  |              |   |            |                                       |                        |
| Tel.: 202-942-5000  |              |   |            |                                       |                        |
| Fax: 202-942-5999   |              |   |            |                                       |                        |
|   |              |   |            |                                       |                        |
| SIGNATURE   |              |   |            |                                       |                        |
| David R. Marsh/Kristan L. Lansbury  |              |   |            |                                       |                        |
| NAME  |              |   |            |                                       |                        |
| 41,408/53,183   |              |   |            |                                       |                        |
| REGISTRATION NUMBER   |              |   |            |                                       |                        |

**ARNOLD & PORTER LLP**

202.942.5000  
202.942.5999 Fax

555 Twelfth Street, NW  
Washington, DC 20004-1206

January 10, 2006

**Mail Stop PCT**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: U.S. National Phase Application  
Based on International Application No. PCT/EP2004/000109  
International Filing Date: 9 January 2004  
Appln. No.: To Be Assigned  
Filed: Herewith  
Title: Autologous Self-Tolerance Inducing Cells of Monocytic Origin and  
Their Use in Pharmaceutical Preparations  
Applicants: Bernd Karl Friedrich KREMER *et al.*  
Atty. Docket: 18724.009

Sir:

The following documents are forwarded herewith for appropriate action by the U.S.  
Patent and Trademark Office as receiving office for the PCT:

1. Transmittal Letter to the United States Designated/Elected Office (DO/EO/US)  
Concerning a Filing Under 35 U.S.C. 371 (in duplicate);
2. a copy of the Published International Application WO 2005/005620 A1, filed

January 9, 2004

and naming as inventors:

Bernd Karl Friedrich KREMER, Fred FÄNDRICH, and Maren SCHULZE  
the application consisting of:

- a specification containing:
  - (i) 65 pages of a description prior to the claims;
  - (ii) 7 pages of claims;
  - (iii) a one page abstract; and

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Commissioner for Patents  
Atty. Dkt.: 18724.009  
January 10, 2006  
Page 2

(iv) 12 pages of drawings (Figures 1-9, 10A, 10B, 11, and 12);

3. a copy of a Combined Declaration and Power of Attorney for Patent Application executed by Bernd Karl Friedrich KREMER, Fred FÄNDRICH, and on behalf of Maren SCHULZE (3 pages);
4. a copy of an Authorization, executed by Maren SCHULZE, granting Power of Attorney to Bernd Karl Friedrich KREMER (1 page);
5. a Preliminary Amendment;
6. a copy of Form PCT/IB/308 (Second and Supplementary Notice Informing the Applicant of the Communication of the International Application);
7. a copy of Form PCT/IB/306 (Notification of the Recording of a Change);
8. a copy of Form PCT/IB/332 (Information Concerning Elected Offices Notified of Their Election); and
9. a copy of Form PCT/IB/308 (First Notice Informing the Applicant of the Communication of the International Application);
10. a copy of a letter to WIPO requesting change of inventor Maren RUHNKE's name to Maren SCHULZE;
11. a copy of Form PCT/IPEA/409 (International Preliminary Report on Patentability); and
12. two (2) return postcards.

Applicants request that \$3,000.00 for the following fees be charged to Deposit Account No. 50-2387, referencing matter number 18724.009:

|                   |                    |
|-------------------|--------------------|
| \$ <u>300.00</u>  | basic national fee |
| \$ <u>200.00</u>  | examination fee    |
| \$ <u>500.00</u>  | search fee         |
| <u>\$2,000.00</u> | excess claims fee. |

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Commissioner for Patents  
Atty. Dkt.: 18724.009  
January 10, 2006  
Page 3

Please stamp one of the two attached postcards with the filing date of these documents and return it to our courier, and stamp the other prepaid postcard with the filing date and unofficial application number and return it as soon as possible.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any fees, other than the above fees (\$3,000) are due in conjunction with this filing. However, if any additional fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387, referencing matter number 18724.009. A duplicate of this letter is enclosed.

Respectfully submitted,



David R. Marsh (Reg. No. 41,408)  
Kristan L. Lansbery (Reg. No. 53,183)

Attachments